

## Agenda

### Pharmacovigilance Workshop

### Barcelona

### October 20th – 21st, 2023

#### Objectives:

To guide the member company representatives on how to prepare a mock AVSS protocol, which could serve as a basis for members to be able to create an AVSS protocol for a real product on their own.

#### Deliverables:

This workshop is an intermediate step for obtaining a mock AVSS protocol. After this Workshop, the participants will

1. Have a general structure of an AVSS protocol for a type of vaccine similar to theirs.
2. Have the knowledge on how to start creating a specific AVSS protocol for a vaccine their company produce.

#### Day 1, October 20<sup>th</sup>, 2023

Time	Title	Responsible
9:00 - 9:30	Welcome to members	Rajinder Suri
9:30 - 10:30	How can AVSS help with vaccine safety issues? Literature examples	Katharina Hartmann Patrícia Mouta
10:30 - 11:00	Discussion	All participants
11:00 - 11:30	<b>Coffee break</b>	
11:30 – 13:00	Talking about AVSS – steps to define if AVSS can help	Patrícia Mouta Katharina Hartmann All participants
13:00 – 14:00	<b>lunch</b>	
14:00 - 15:30	Group activity – building an AVSS project. Group 1 Group 2	Patrícia/Viska + group 1 Katharina + Group 2
15:30 – 16:00	<b>Coffee Break</b>	
16:00 – 17:00	Continuation: Group activity – building an AVSS project. Group 1 Group 2	Patrícia/Viska + Group 1 Katharina + Group 2
17:00 – 18:00	Wrap up day one	
19:00	Dinner	TBC

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Day 2, October 21<sup>st</sup>, 2023

October 21	Title	Responsible
9:00 - 9:30	Briefing day 2	Patrícia/Katharina
9:30 – 10:30	Group 1 presentation	Group 1 / Moderator – Patrícia/Viska
10:30 - 11:00	Coffee break	
11:00 – 12:00	Group 2 presentation	Group 2/ Moderator – Katharina
12:00 – 13:00	What have we learned? Create a brief report (maybe a SWOT matrix)	All participants
13:00 – 14:00	Lunch	
14:00 – 15:00	Phase IV: Study protocol preparation and review. Discussion of the final step of the project: Challenges, progress and timelines.	Patrícia/Viska/Katharina / PV Group
15:00 - 15:30	Coffee break	
15:30 to 16:30	General Pharmacovigilance challenges in LMICs – Discussion points from DCVMN companies	All participants
16:30 to 17:00	Debriefing Day 2 and next steps	Patrícia/Viska and PV Group

### Group Activity: Building an AVSS project (days 1 and 2, as agenda)

#### Objective:

To understand the importance of active surveillance in detecting, assessing, and managing vaccine safety concerns.

This activity aims to provide participants with hands-on experience in designing and implementing an active vaccine surveillance protocol. It emphasizes the importance of timely data collection, rigorous analysis, and effective risk communication in managing vaccine safety concerns.

#### Background Scenario:

A new vaccine, "VaxProtect," will be introduced in the national immunization program. Post-marketing, there have been sporadic reports of a rare adverse event following immunization (AEFI) associated with this vaccine. The health authority decided to implement an active vaccine surveillance protocol to assess the safety concern.

#### Materials Needed:

- Vaccine profile (clinical trials, pre-clinical data)

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- Data analysis tools (e.g., software like Excel or a statistical package)
- Literature (disease, vaccine platform, others)

### Steps:

#### Day 1:

1. Group Formation (20 minutes)
  - Divide participants into 2 small groups.
  - Assign each group a specific product/case scenario.
2. Introduction (30 minutes)
  - Brief participants about the background scenario. (Present the case)
3. Defining if AVSS can help and how – research question, gaps of data, how to search literature, ... (45 minutes)
4. Designing the Surveillance Protocol (1,5 hour)
  - Each group designs a possible protocol proposal to actively monitor their assigned population. (Follow steps)
  - Consider factors like sample size, data sources, data collection methods, and duration of surveillance.

#### Day 2:

5. Feedback and Discussion (30 minutes presentation + 30 minutes discussion per group)
  - Each group presents their findings and protocol design.
  - Facilitator provides feedback and highlights best practices.
  - Open floor discussion on challenges faced and lessons learned.
6. Conclusion (60 minutes) What have we learned?
  - Summarize the importance of active vaccine surveillance in addressing safety concerns.
  - Discuss real-world examples where active surveillance made a difference.